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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/604,504

07/25/2003

Clark C. Davis

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/604,504	<b>Applicant(s)</b> DAVIS ET AL.	
	<b>Examiner</b> Brian Szmaj	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18,25,27,53-59 and 82-87 is/are pending in the application.
- 4a) Of the above claim(s) 54,56 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,25,27,53-55,58,59 and 82-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 25, 27, 53, 55, 58, 59 and 82-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531) as evidenced by Hernandez et al (5,396,212).

Jacobsen et al disclose a coronary guidewire system and further disclose a tubular member (514) having a proximal end and a distal end, and having a plurality of slots configured to make the tubular member (514) more flexible in bending; a core wire extending proximally from the tubular member, the core wire being attached with a joint to the tubular member at least at the proximal end; a helical coil formed of radiopaque wire (see Figures 15-17; Column 11, lines 66-67; and Column 12, lines 1-5); a core wire (501), at least part of the core wire being located inside the tubular member (514), at least a portion of the core wire (501) being located inside the first coil (see Figures 15-17); the core wire (501) being attached with a joint to the first tubular member (514) at least at the proximal end, the joint comprising a first coil circumscribing the core wire

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(501), the coil being at least partially inside the first tubular member (514), and the joint comprises at least one of solder and adhesive (see Column 12, lines 9-34); the core wire (501) having a tapered portion, the joint being located at least partially within the tapered portion (see Figures 14 and 18); the core wire (501) comprising an abrupt change in diameter between the proximal end and the distal end (see Figure 14); radiopaque material inside the tubular member (514), at or adjacent to the distal end of the tubular member (514) (see Figure 18; Column 11, lines 66-67; and Column 12, lines 1-11); the core wire (501) being attached to the tubular member (514) at the distal tip (520) of the core wire (501); and the core wire (501) having at least one abrupt change in cross-sectional dimension, the abrupt change being at or adjacent to the joint (see Figures 14-18).

Jacobsen et al, however fail to disclose the coil being formed from a wire having a substantially non-circular cross section, the cross section having a greater dimension in the radial direction than in the axial direction, wherein prior to winding, the wire has two substantially flat opposite non-parallel sides that are out of parallel by an angle, and after winding into the coil, the sides are substantially parallel.

Shiber discloses a guided atherectomy system and further discloses the coil being formed from a wire having a substantially non-circular cross section, the cross section having a greater dimension in the radial direction than in the axial direction, and after winding into the coil, the sides are substantially parallel. See Figure 11; and Column 6, lines 45-56.

One of ordinary skill in the art would recognize Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section. In order to obtain the rectangular cross section as taught by Shiber, the wire would have to initially be of a trapezoidal shape before being formed into the coil, because if the wire was initially of a rectangular cross section, the formed coil would be formed into a trapezoidal cross section due to the increase of material on the inside of the formed coil. Hernandez et al discloses a means for winding transformer wire and further discloses the fact that a wire having a rectangular cross-section prior to bending about a radius would become a wire with a trapezoidal cross-section after bending about a radius. See Column 2, lines 53-63 of Hernandez et al. Therefore, Shiber implicitly discloses the use of a trapezoidal shaped flat stock prior to winding into a coil to form the shown rectangular cross-section.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Jacobsen et al to include the use of a non-circular cross section, as per the teachings of Shiber, since the substitution of a non-circular cross-section coil in the place of a circular cross-section coil would provide the predictable result of being able to navigate a guidewire through the vasculature of the patient.

4. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531) as evidenced by Hernandez et al (5,396,212) in view of Levine et al (2003/0009157 A1).

Jacobsen et al and Shiber et al, as discussed above, disclose a guidewire comprising a tubular member that can comprise rounded edges to prevent the device from catching on tissue during use (see Paragraph 0098 in Jacobsen et al) and a radiopaque coil created by edge winding a wire with a substantially non-circular cross section, but fail to disclose the use of a chamfer.

Levine et al disclose a flexible flow apparatus and further disclose the use of a chamfer. See Paragraph 0153.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jacobsen et al and Shiber to include a chamfer, as per the teachings of Levine et al, since it would also provide a means of minimizing the likelihood of the guidewire catching tissue during withdrawal from the body.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531) as evidenced by Hernandez et al (5,396,212) in view of Boyle et al (2003/0105484 A1).

Jacobsen et al and Shiber et al, as discussed above, disclose a guidewire comprising a tubular member that can comprise rounded edges to prevent the device from catching on tissue during use (see Paragraph 0098 in Jacobsen et al) and a radiopaque coil created by edge winding a wire with a substantially non-circular cross section, but fail to disclose the use of a proximal chamfer.

Boyle et al disclose an intraluminal device and further disclose a proximal chamfer (40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jacobsen et al and Shiber to include a proximal chamfer, as per the teachings of Boyle al, since it would also provide a means of minimizing the likelihood of the guidewire catching tissue during withdrawal from the body.

### ***Response to Arguments***

6. Applicant's arguments filed July 21, 2008 have been fully considered but they are not persuasive.

The Applicants argue with regards to independent Claims 25 and 53, one would not be able to substitute the coil of Jacobsen et al with the coil of Shiber et al due to the different functions of the coils, and further cite the KSR decision stating: "substituting a screw for a nail is not likely to yield a non-obvious invention". The Examiner respectfully disagrees. See the previous Office Action with respect to the rejection of these claims. The Applicant is invited to schedule an interview with the Examiner for further explanation with respect to the KSR rejection, if the Applicants feel an interview would further prosecution of the case.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736